

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant | : Jan Weber et al. | Art Unit | : 3731 |
| Serial No. | : 10/670,433 | Examiner | : Melanie R. Tyson |
| Filed | : September 24, 2003 | Conf. No. | : 2417 |
| Title | : MAGNETIC DEVICE WITH MARKERS FOR MAGNETIC RESONANCE VISIBILITY | | |

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Commissioner for Patents

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Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants submit this request under the Pre-Appeal Conference Pilot Program described in the U.S. Patent and Trademark OG Notice, "New Pre-Appeal Brief Conference Pilot Program," dated July 12, 2005 and extended until further notice as of January 10, 2006. This request is being filed with a Notice of Appeal. Applicants request review of the matters discussed below by a panel of examiners, because the rejections under 35 U.S.C. §§ 102 and 103 are without basis.

In the interest of furthering prosecution, Applicants previously filed a response to the final Office action of June 12, 2007 canceling claims 12-18 without prejudice. Applicants request entry of those claim cancellations pursuant to 37 C.F.R. 1.116(b)(1), which states that after a final action, "[a]n amendment may be made canceling claims." No claim amendments accompany the instant Pre-Appeal Brief Request for Review. A Petition for a three-month extension of time to and including December 12, 2007 accompanied the previously-filed response to the final Office action.

Claims 1-11 and 19-40 are pending in this application. Of these, claims 1, 19, 30 and 34 are independent in form. Independent claims 1 and 34 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0100830 (Zhong et al.). Independent claim 30 was rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,921,414 (Klumb et al.) in view of Zhong et al. Independent claim 1 was also rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,361,759 (Frayne et al.). Various dependent claims are rejected under 35 U.S.C. §102(b) or in the alternative 35 U.S.C. §103(a) as either anticipated by Zhong et al. or being obvious over Klumb et al. in view

of Zhong et al. Applicants ask that the panel review the §102 and §103 issues below, which Applicants submit will dispose of the entire appeal. Applicants reserve the right to expand these issues and or present new issues should they subsequently file an appeal.

Claim 1 recites “a magnetic material at least embedded into at least part of the support structure.” The Office action interpreted the claim term “embedded” to mean “deeply and solidly lodged.” See Office action, p.8, citing Encarta World Dictionary. Furthermore, the Office action states that “[o]n a microscopic level, the surface of [Zhong's] medical device, or stent, is uneven, or in other words comprises peaks and valleys.” Id. The Office action concluded, “[t]herefore, the magnetic coating of Zhong would be deeply and solidly lodged in the valleys between the peaks or ‘embedded into at least part of the support structure.’” Id.

In rejecting the claims the Examiner asserts that “coating” has an analogous meaning to “embedding.” But this is inconsistent with the art cited by the Examiner and is not how one of skill in the art would interpret the two terms. The Manual of Patent Examining Procedures (MPEP) states that claims are to be given their broadest reasonable construction in light of the specification “as it would be interpreted by one of ordinary skill in the art.” MPEP, § 2111, citing In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364 (Fed. Cir. 2004). The Zhong et al. publication itself makes clear that, to a person of ordinary skill in the art, “embedded” has a different meaning than “coated.”

Indeed, the Background section of Zhong et al. identifies several reasons why magnetic material should not be embedded into implantable medical devices. More particularly, the Background section discusses an earlier patent that allegedly discloses, “embedded ferromagnetic particles . . . to make [a] catheter visible under MRI by providing contrast with respect to the surrounding body tissues.” (Emphasis added). The Background section identifies numerous drawbacks associated with the embedded ferromagnetic particles, stating that:

“[t]he direct incorporation of ferromagnetic or paramagnetic materials into the polymeric material of . . . implantable or insertable medical devices, however, suffers from numerous drawbacks. For example, in order to provide enhanced contrast under MRI, paramagnetic materials, such as paramagnetic ions, require the proximity of water or another proton-bearing substance.... Moreover, the incorporation of such ferromagnetic or paramagnetic materials can detrimentally affect the requisite mechanical properties, such as strength and

flexibility, of the polymeric materials used to construct the implantable or insertable medical device.”

(Zhong, ¶ 0009)

The Background section of Zhong et al. concludes that “there remains a need for [an] approach that avoids the disadvantages of the methods discussed above.” Then, the Zhong et al publication discloses, presumably in an attempt to overcome the drawbacks identified in the excerpted passage above, coating an implantable medical device with a hydrogel polymer that is adapted to incorporate a paramagnetic material. (Zhong, ¶53; see also Zhong, ¶¶ 26, 29, and 46). It is clear, therefore, that whatever Zhong’s “coating” method might include, it does not include “embedding.” Moreover, in view of the foregoing observations, it is clear that a person of ordinary skill would readily recognize that “embedded” means something different than “coated.”

Claim 1 should be allowable over the Zhong et al. publication for at least the foregoing reasons. Claims 2, 3, 5 and 6 depend from claim 1 and, therefore, should be allowable over the Zhong et al. publication for at least the same reasons as claim 1.

Claims 34, 36 and 38 are rejected under 35 U.S.C. §102(e) as being anticipated by the Zhong et al. publication. Claim 34 recites features that are similar to those discussed above with respect to claim 1. In particular, claim 34 recites a stent with magnetic material at least “embedded” into metallic material. As discussed above with reference to claim 1, the Zhong et al. publication does not disclose that feature. Claim 34 should be allowable for at least that reason. Claims 36 and 38 depend from claim 34 and, therefore, should be allowable for at least the same reasons as claim 34.

Claims 10, 11, 39 and 40 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over the Zhong et al. publication. Applicants disagree with those rejections. Claims 10 and 11 depend from claim 1, which recites “a magnetic material at least embedded into at least part of the support structure.” For at least the reasons discussed above, the Zhong et al. publication does not disclose or render obvious the claimed subject matter. Similarly, claims 39 and 40 depend from claim 34, which recites a stent with magnetic material at least “embedded” into metallic material. For at least the reasons discussed above, the Zhong et al. publication does not disclose or render obvious the claimed

subject matter. Claims 10, 11, 39 and 40 should be allowable over the Zhong et al. publication for at least the foregoing reasons.

Claims 8 and 37 are rejected 35 U.S.C. §103(a) as being obvious over the Zhong et al. publication. Applicants disagree with those rejections. Claim 8 depends from claim 1, which recites “a magnetic material at least embedded into at least part of the support structure.” (Emphasis added) For at least the reasons discussed above, the Zhong et al. publication does not disclose or render obvious the claimed subject matter. Similarly, claim 37 depends from claim 34, which recites a stent with magnetic material at least “embedded” into metallic material. For at least the reasons discussed above, the Zhong et al. publication does not disclose or render obvious the claimed subject matter. Claims 8 and 37 should be allowable over the Zhong et al. publication for at least the foregoing reasons.

Claims 30-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,921,414 (Klumb et al.) in view of the Zhong et al. publication. Claims 30 recites “a magnetic material at least embedded into [a] segment.” (Emphasis added). As discussed above, the Zhong et al. publication clearly does not disclose or suggest the claimed subject matter. Nor does the Klumb et al. patent disclose or suggest the claimed subject matter.

The Klumb et al. patent merely discloses a prosthesis with a coiled body and a graft material covering at least part of the coiled body. See Abstract. The Klumb et al. patent clearly does not disclose or suggest “a magnetic material at least embedded into [a] segment,” as recited in claim 30. The Office action itself concedes this point. (Office action, p. 6, ¶ 8 “Klumb et al. do not disclose . . . that magnetic material is at least embedded into the segment.”)

Claim 30 should be allowable over Klumb et al. in view of Zhong et al. for at least the foregoing reasons. Claims 31-33 depend from claim 30 and, therefore, should be allowable over Klumb et al. in view of Zhong et al. for at least the same reasons as claim 30.

Claims 1, 7 and 9 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,361,759 (Frayne et al.). Applicants respectfully request reconsideration and withdrawal of those rejections for at least the following reasons.

First, claim 1 recites “a magnetic material at least embedded into at least part of the support structure.” (Emphasis added). In contrast, the Frayne et al. patent discloses an MRI

signal-emitting coating. (See, e.g., Frayne et al.'s title). More particularly, Frayne et al. discloses a medical device that is coated with a polymer coating and then soaked in a solution to allow paramagnetic ions to react with the polymer coating. (See Frayne, Col. 8, lines 4-14 and 48-55). As discussed above, a person of ordinary skill in the art would clearly recognize that the term "embedded" means something different than "coated."


Claim 1 should be allowable over the Frayne et al. patent for at least the foregoing reasons. Claims 7 and 9 depend from claim 1 and, therefore, should be allowable over the Frayne et al. patent for at least the same reasons as claim 1.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any charges or credits to Deposit Account No. 06-1050.


Respectfully submitted,

Date: 12-10-07



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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number: 10527-626001 |
| I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop AF, Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450. _____ Date of Deposit _____ Signature _____ Typed or Printed Name of Person Signing Certificate | Application Number 10/670,433 | Filed September 24, 2003 |
| | First Named Inventor Jan Weber et al. | |
| | Art Unit 3731 | Examiner Melanie R. Tyson |
| | | |
| <p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a Notice of Appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record (Reg. No.) 59,005</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p style="text-align: right;">  _____ Signature _____ William P. O'Sullivan Typed or printed name _____ (212) 765-5070 Telephone number _____ December 10, 2007 Date </p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p> | | |
| <input checked="" type="checkbox"/> Total of 1 forms are submitted. | | |